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December 13, 1999

Document Management Branch (HFA-305) Food and Drug Administration 5630 Fisher Lane, Room 1061 Rockville, MD 20852

Dear Sirs

It has recently been brought to my attention that the September 30, 1999 issue of the Federal Register contains a proposed FDA regulation that would permit FDA regulation of allograft tissue. I refer to Docket No. 97N-484S.

It is not my intent to oppose safe regulation of tissue from an appropriate agency. However, to attempt to classify tissue, such as bone tissue, as a medical device is an inappropriate step and will (if passed) result in additional medical delays and availability as well as additional cost to the public. I, therefore, am opposed to adoption of this proposed regulation as written.

Larry Grant

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